

**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF TEXAS  
FORT WORTH DIVISION**

MERIAL LIMITED and BASF AGRO B.V.,  
ARNHEM (NL), WÄDENSWIL BRANCH,

Plaintiffs,

v.

VIRBAC S.A. and VIRBAC  
CORPORATION,

Defendants.

Civil Case No. 4:10-cv-181-Y

**DEFENDANTS' AMENDED OBJECTION TO MAGISTRATE'S ORDER  
GRANTING MOTION TO COMPEL AND ENTERING PROTECTIVE ORDER**

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Pursuant to Federal Rule of Civil Procedure 72(a), Defendants Virbac S.A. and Virbac Corporation (collectively "Virbac" or "Defendants") respectfully submit this Amended Objection to Magistrate Judge Cureton's Order Granting Plaintiffs' Motion to Compel and Entering Protective Order (Doc. No. 40) as follows:

**I.**  
**INTRODUCTION**

On June 10, 2010 Magistrate Judge Cureton issued an order which allows Dr. Judy Jarecki-Black, in-house counsel for Plaintiff Merial Limited ("Merial"), access to Virbac's most sensitive and highly-confidential business information and documents. *See* (Doc. No. 40 at 14, App. 14; Doc. No. 50 at ¶ 8(e), App. 5).

Because Dr. Jarecki-Black is a competitive decision maker, her access to these items has the potential to cause severe harm to Virbac. Denying Dr. Jarecki-Black access to these items will not prevent Merial from prosecuting its lawsuit. For these reasons, Virbac respectfully objects to the Court's Order of June 10, 2010 and requests that the Court reconsider its decision granting Dr. Jarecki-Black access to documents and information classified as CONFIDENTIAL ATTORNEYS' EYES ONLY—Virbac's most sensitive and guarded business information—and that the Court deny Dr. Jarecki-Black access to these items.

Magistrate Judge Cureton has also overruled Virbac's objections to Merial's Interrogatory No. 11 and Request for Production Nos. 3 and 8, and ordered Virbac to fully respond to these requests.<sup>1</sup> (Doc. No. 40 at 14-15, App. 14-15).

Interrogatory No. 11 and Request for Production No. 3 seek the identity of Virbac's highly-confidential fipronil source. Because this source may be the only source available

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<sup>1</sup> Virbac is supplementing its answers to Merial's Interrogatories and producing documents in accordance with the Court's June 10, 2010 Order, and will serve Merial with these supplementations and documents on June 17, 2010. *See* (Doc. No. 40 at 14-15, App. 14-15).

anywhere in the world that is not infringing any of Merial or BASF's patents, any disclosure of this source to Merial, for any reason, could irreparably harm Virbac. Because this source cannot be held liable for contributory infringement or for inducement, maintaining the source's confidentiality will not prejudice Merial. Further, any importation issues related to the amount of fipronil brought into the United States can be answered by Virbac S.A. Virbac S.A. sourced the subject fipronil, formulated it into finished products, and imported these finished products into the United States for use in four studies. The source only supplied the fipronil to Virbac S.A., outside of the United States. It is extremely important to Virbac that its fipronil source not be disclosed to Dr. Jarecki-Black under any circumstances.

Request for Production No. 8 seeks documents related to Virbac's fipronil-only EFFIPRO® product. This product is not at issue in this litigation and was not related to the U.S. studies that are the subject of this infringement action. This is a product that was developed outside of the United States. It is also sold exclusively outside of the United States. Because of this, Merial will not be prejudiced in any way if it is denied access to these documents. There is no reason why Merial needs information relating to competing, noninfringing products to prosecute its claims in this lawsuit. Given the harm to Virbac if these documents were disclosed inadvertently or otherwise, Virbac should not have to produce these items.

For these reasons, Virbac respectfully objects to the Court's Order and requests that the Court reconsider its decision overruling Virbac's objections to Merial's Interrogatory No. 11 and Request for Production Nos. 3 and 8 and ordering Virbac to fully respond to the requests, and that it be allowed to withhold the identity of its fipronil source and documents and information relating to noninfringing products that are not at issue in this litigation.<sup>2</sup>

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<sup>2</sup> Virbac will disclose the amount of fipronil imported and used in the United States.

**II.**  
**FACTS**

Between 2007 and 2008, Virbac performed four studies of fipronil-containing compositions in the United States (the "U.S. studies"). Karst Dec., June 11, 2010 at ¶¶ 21, 26, 29 App. 33-34. These studies involved compositions developed by Virbac combining fipronil, and a second active ingredient, and are the only studies at issue in this litigation. *Id.* At the time these studies were initiated, Virbac mistakenly believed that the safe harbor research exemption provided by 35 U.S.C. § 271(e)(1), for performing research and tests necessary to obtain FDA regulatory approval, also applied to research and tests necessary to obtain EPA regulatory approval, as is required for fipronil containing pesticides. *See id.* This was a misunderstanding by Virbac in its efforts to comply with the numerous, and often conflicting, regulations and laws of the many countries in which it performs tests. *Id.*

Virbac did not realize that the U.S. studies were excluded from the safe harbor exemption until after they were started. Karst Dec., June 11, 2010 at ¶ 28 App. 34. Since becoming aware that the exemption does not apply to U.S. studies, Virbac has not initiated any fipronil-related studies in the U.S., and has not used any of the results obtained from the U.S. studies for the development and registration of its fipronil-based products. *Id.* at ¶ 29, App. 34.

Virbac has not benefited from the U.S. studies with respect to its fipronil-only EFFIPRO® products, as it was not required to conduct these studies for purposes of obtaining EPA approval of this product. Butz Dec. at ¶ 26, App. 43. Further, these studies are irrelevant to a fipronil-only product, as they involved a combination product containing fipronil and a second active ingredient. *Id.* As such, they could not be used to support an EPA registration of a fipronil-only product, or to support the registration of such product in any country outside of the United States.

The formulation of Virbac's fipronil-only product is different than the formulation of its combination product, the product that was the subject of the U.S. studies at issue in this litigation. Karst Dec., June 11, 2010 at ¶¶ 18, 20, 32, App. 33, 35. Therefore, studies on a combination product would not be relevant to the design and development of a fipronil-only EFFIPRO® product. Butz Dec. at ¶ 26, App. 43. Virbac's activities with respect to its fipronil-only EFFIPRO® product are irrelevant and completely outside of the scope of the '940 patent and this litigation. Therefore, Merial does not need these items to pursue its claims with respect to the '940 patent and Virbac should not have to disclose these items to Merial.

**III.**  
**ARGUMENT**

Under Rule 72(a), this Court "must . . . modify or set aside any part of Magistrate Judge Cureton's order "that is clearly erroneous or is contrary to law." This Court should consider *de novo* whether the order is contrary to law. *See Cont. Cas. Co. v. Am. Home Assur. Co.*, 2010 WL 692942, at \*4 (S.D. W. Va. Feb. 23, 2010) (district court reviews magistrate judge's application of legal principles *de novo* under Rule 72(a)). As explained below, the order is contrary to Dr. Jarecki-Black's status as a competitive decision maker and requires Virbac to produce highly-confidential and sensitive documents and information, the nondisclosure of which will not prevent Merial from bringing its claims.

**A. Dr. Jarecki-Black should not be allowed access to Virbac's most sensitive documents and information.**

Virbac has presented substantial evidence demonstrating that Dr. Jarecki-Black is a competitive decision-maker, such that the Magistrate Judge erred in ordering that she have access to Virbac's highly-confidential information. Dr. Jarecki-Black's active involvement in negotiating settlements and license agreements, as well as her prosecution of patents owned by Merial, all establish that she participates in Merial's business-related decisions. *See Fairchild Defendants' Amended Objection to Magistrate's Order Granting Motion To Compel and Entering Protective Order*

*Semiconductor Corp. v. Third Dimension Semiconductor, Inc.*, No. 08-158, 2009 WL 1210638, at \*10 (D. Me. Apr. 30, 2009). As such, Virbac has shown that Dr. Jarecki-Black is a competitive decision-maker and that it is therefore entitled to protection against her review of its highly-confidential information.

The documents Virbac seeks to protect contain information on competing products, which could be used by Merial to gain a competitive advantage over Virbac if disclosed. They also contain details regarding the highly-confidential source of Virbac's fipronil, which is irrelevant to any issues in this litigation, as fully explained herein. There is an undeniably high risk of inadvertent disclosure when in-house counsel of Dr. Jarecki-Black's position and skill are given access to a competitor's confidential information. *See generally Amsted Indus., Inc. v. Nat'l Castings, Inc.*, No. 88-C924, 1988 WL 90022 (N.D. Ill. Aug. 22, 1988). Those risks would continue far beyond the scope of this Court's resolution of the present dispute. Therefore, Virbac respectfully objects to the Court's Order of June 10, 2010 and requests that the Court reconsider its decision granting Dr. Jarecki-Black access to documents and information classified as CONFIDENTIAL ATTORNEYS' EYES ONLY and that the Court deny Dr. Jarecki-Black access to these items.

**B. Virbac should not be required to disclose documents and information relating to its fipronil source or to noninfringing, competing products.**

Considering Merial's Interrogatory No. 11 and Request for production Nos. 3 and 8, there are two categories of documents and information at issue. The first category relates to Virbac's fipronil source and is the subject of Interrogatory No. 11 and Request for production No 3. The second relates to Virbac's fipronil-only EFFIPRO® product, which was not tested in the U.S. studies that are the subject of this infringement suit, and is the subject of Request for Production No. 8.

While Virbac does not believe that Dr. Jarecki-Black should have access to any of its CONFIDENTIAL ATTORNEYS' EYES ONLY information, should the Court order Virbac to produce these items, it would request that Dr. Jarecki-Black be excluded from access to these two specific categories of documents and information.

**1. Virbac's fipronil source is not at issue in this litigation.**

In its Motion to Compel, Merial argues that it is "entitled to discovery relating to the sources of the infringing fipronil unlawfully imported into the United States so as to determine, for example, whether any of Defendants' suppliers are liable to Plaintiffs for inducement or contributory infringement." Mot. Compel (Doc. No. 29) at 18. Because Merial will not be able to substantiate a claim against Virbac's fipronil source for either inducement or contributory infringement, it does not need this information to litigate its claims against Virbac. To the contrary, should this source be disclosed, Virbac could be irreparably injured.

Virbac sourced the fipronil at issue in this suit outside of the U.S. Karst Dec., June 17, 2010 at ¶ 6, App. 44-45. Virbac, not the source, then shipped the fipronil-containing products to the U.S. *Id.* Virbac strongly believes that its source of fipronil may be the only one available in the world that does not infringe any of Merial or BASF's patents. *Id.* at ¶7, App. 45. The source has been used by Virbac commercially in Europe for over a year. *Id.* In April 2008, Virbac disclosed an audit and chemical expert report to Dr. Jarecki-Black which certified the synthesis process used by the source, and confirmed that it would not infringe any of Merial or BASF's European patents. *Id.* at ¶ 8, App. 45. Neither Merial nor BASF has pursued any legal action against Virbac in Europe. *Id.*

Any disclosure of its fipronil source to Merial could lead to irreparable harm to Virbac. *Id.* at ¶ 9, App. 45. For example, should the source be disclosed, and should a competitor of Virbac propose to the source to buy all of the source's production capacity, this would have the

effect of eliminating Virbac's future supply of fipronil. *Id.* Further, as this is the only source described and authorized in the registration dossiers of Virbac's fipronil-containing EFFIPRO® products, both in Europe and in the United States, which provide Virbac with the necessary regulatory approval to sell its fipronil-containing products, Virbac could be prevented from selling its EFFIPRO® products, which are products not at issue in this litigation. *Id.* at ¶¶ 9-10, App. 45. These products, which were launched in mid-2009 and are currently being sold exclusively in Europe, already represent Virbac's number one product, based on sales. *Id.* at ¶ 10, App. 45.

**a. Virbac's fipronil source cannot be held liable as a contributory infringer.**

Contributory infringement is defined under 35 U.S.C. § 271(c) as follows:

Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination, or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

35 U.S.C. § 271(c). "In order to succeed on a claim of contributory infringement, in addition to proving an act of direct infringement, a plaintiff must show that [the manufacturer] 'knew that the combination for which its components were especially made was both patented and infringing' and that [the manufacturer's] components have 'no substantial non-infringing uses.'"

*Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293, 1312 (Fed. Cir. 2005) (quoting *Golden Blount, Inc. v. Robert H. Peterson Co.*, 365 F.3d 1054, 1061 (Fed. Cir. 2004)).

Virbac's fipronil supplier did not offer to sell or sell its product to Virbac in the U.S. Karst Dec., June 17, 2010 at ¶ 6, App. 44-45. Nor did it import its product into the U.S., as required by § 271(c). *Id.* Virbac's supplier is not located in the U.S. and its fipronil is not

manufactured in the U.S. *Id.* All transactions between Virbac and its supplier were negotiated and consummated outside the jurisdiction of the U.S. *Id.* Virbac solely conducted the fipronil importation into the U.S. *Id.*

When confronted with essentially the exact same facts, numerous courts have held manufacturers were not liable for any type of infringement. *See, e.g., Cybiotronics, Ltd. v. Golden Source Elecs., Ltd.*, 130 F. Supp. 2d 1152 (C.D. Cal. 2001); *Pfizer, Inc. v. Aceto Corp.*, 853 F. Supp. 104 (S.D.N.Y. 1994). In both *Cybiotronics* and *Pfizer*, the manufacturers sold their products to a separate party, who subsequently imported the products into the United States. *See Cybiotronics*, 130 F. Supp. at 1175; *Pfizer*, 853 F. Supp. at 106. In both instances, the courts concluded the manufacturer could not be held liable for any type of infringement, because all elements of the transactions took place outside the jurisdiction of the United States and the manufacturers were not the ones who actually imported the products into the United States. *See Cybiotronics*, 130 F. Supp. at 1175; *Pfizer*, 853 F. Supp. at 106.

Furthermore, Merial cannot show Virbac's supplier manufactured its product with the intent to interfere with the '940 patent. Contributory infringement doctrine "absolves the equivocal conduct of selling an item with substantial lawful as well as unlawful uses, and limits liability to instances of more acute fault than the mere understanding that some of one's products will be misused. It leaves breathing room for innovation and a vigorous commerce." *Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd.*, 545 U.S. 913, 932-33 (2005) (citing *Sony Corp. v. Universal City Studios*, 464 U.S. 417, 442 (1984); *Dawson Chemical Co. v. Rohm & Haas Co.*, 448 U.S. 176, 221 (1980); *Henry v. A.B. Dick Co.*, 224 U.S. 1, 48 (1912)).

The operative phrasing in 35 U.S.C. §271(c) regards selling an item "constituting a material part of the invention . . . especially made or especially adapted for use in an

*infringement of [the] patent,"* and that part being "not a staple article . . . suitable for substantial noninfringing use." 35 U.S.C. § 271(c) (emphasis added). Virbac's fipronil supplier produces the composition in a noninfringing manner outside the United States. Karst Dec., June 17, 2010 at United States 6, App. 44-45. Because a European market exists for fipronil and Virbac conducts business in that market using fipronil purchased from its supplier, Merial cannot show Virbac's supplier manufactured the fipronil "especially . . . for use in the infringement of [the '940] patent" in the United States. *Id.*; *see also id.*

Merial's question as to possible contributory infringement does not contain any facts sufficient to raise its claim to relief under § 271(c) above a 'speculative' level. *See Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007). Therefore, a claim of contributory infringement is not "plausible on its face." *See id.* at 570. Because contributory infringement liability is not plausible and Virbac solely imported the fipronil into the United States, identification of the source of its fipronil is not relevant to Merial's claims. *See Fed. R. Civ. P.* 26(b)(1). Accordingly, Virbac requests that the court sustain its objections to Interrogatory No. 11 and request for Production No. 3 and allow it to withhold the identity of its fipronil source.

**b. Virbac's fipronil source cannot be held liable for inducement of infringement.**

A party is liable for inducement of infringement if it "actively induces infringement of a patent." 35 U.S.C. § 271(b). Virbac's supplier can only be liable under this provision if it actively and knowingly aided or abetted Virbac's infringement of the '940 patent. *See Nat'l Presto Indus., Inc. v. West Bend Co.*, 76 F.3d 1185, 1194 (Fed. Cir. 1996) ("The statutory liability for inducement of infringement derives from the common law, wherein acts that the actor knows will lead to the commission of a wrong by another, place shared liability for the wrong on the actor.").

As discussed, a legal European market exists for fipronil and Virbac conducts business in that market using fipronil purchased from its supplier. Karst Dec., June 17, 2010 at ¶ 6, App. 44-45. Therefore, there is a substantial noninfringing use for the fipronil which Virbac purchases outside of the United States. *See Organon Inc. v. Teva Pharms., Inc.*, 35 F.3d 1576, 1580 (Fed. Cir. 1994). Courts have articulated a "safe harbor" rule for companies selling products with substantial noninfringing uses. *See, e.g., MGM Studios Inc. v. Grokster, Ltd.*, 545 U.S. 913, 937 (2005); *Ricoh Co., Ltd. v. Quanta Computer Inc.*, 550 F.3d 1325, 1340 (Fed. Cir. 2008). Because Virbac's source cannot be liable for inducement, Virbac should not be forced to disclose the source's identity.

**2. Merial does not need documents and information relating to noninfringing, competing products to pursue its claims.**

Request for Production No. 8 seeks documents related to Virbac's fipronil-only EFFIPRO® product which is not at issue in this litigation and was not involved in the U.S. studies that are the subject of this infringement action. Karst Dec., June 17, 2010 at ¶ 10, App. 45. Merial will not be prejudiced in any way if it is denied access to these documents. There is no reason why Merial needs information relating to competing, noninfringing products to bring its claims. Given the harm that could come to Virbac if these documents were inadvertently disclosed, Virbac should not have to produce these items.

For these reasons, Virbac respectfully objects to the Court's Order and requests that the Court reconsider its decision overruling Virbac's objections to Merial's Interrogatory No. 11 and Request for Production Nos. 3 and 8 and ordering Virbac to fully respond to the requests, and that it be allowed to withhold the identity of its fipronil source and documents and information relating to noninfringing products that are not at issue in this litigation. Should the Court order

Virbac to produce these items, it would request that Dr. Jarecki-Black be excluded from access to these two specific categories of documents and information.

**IV.  
CONCLUSION**

Wherefore, Virbac requests that its Motion be granted, that Dr. Jarecki-Black be denied access to Virbac's CONFIDENTIAL ATTORNEYS' EYES only documents and information, that the Court sustain its objections to Merial's Interrogatory No. 11 and Request for Production Nos. 3 and 8, that it be allowed to withhold the identity of its fipronil source and documents and information relating to noninfringing products that are not at issue in this litigation, and for all other relief to which it may be entitled.

Respectfully submitted,

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CORPORATION

**CERTIFICATE OF CONFERENCE**

On June 16, 2010, Jason Wietjes, counsel for Defendants, and Patrick Elsevier, counsel for Plaintiffs, conferred regarding this Motion and the relief sought herein. Counsel for Plaintiffs stated that Plaintiffs are opposed to the Motion and the requested relief.

s/ Jason A. Wietjes  
Jason A. Wietjes

**CERTIFICATE OF SERVICE**

I hereby certify that a true and correct copy of the foregoing document has been forwarded to all counsel of record via the Court's electronic filing system pursuant to the Federal Rules of Civil Procedure on the 17<sup>th</sup> day of June, 2010.

s/ Michael D. Pegues  
Michael D. Pegues